

10/540302

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Customer No.: 07278

Docket No.: 04393/0203024-US0

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Kunihiro Ohta et al.

Serial No.: Not yet assigned

Filed: Concurrently herewith

For: THE METHOD OF INDUCING HOMOLOGOUS RECOMBINATION  
OF SOMATIC CELL  
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June 21, 2005

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted in accordance with 37 C.F.R. 1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed: (Check one of the boxes A-D)

- ☒ A. Within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application.
- ☐ B. before the mailing date of a first office action on the merits, or a first office action after filing a request for continued examination.
- ☐ C. after (A) and (B) above, but before final rejection or allowance, and Applicants have made the necessary statement in box "i" below or paid the necessary fee in box "ii" below.

(check one of the boxes "i" and "ii" below:)

- ☐ i. Counsel states that, upon information and belief, each item of information listed herein was either (a) first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.
- ☐ ii. A check for the fee set forth in 1.17(p), presently believed to be \$180, is enclosed.
- ☐ D. after (A), (B) and (C) above, but before payment of the issue fee: Applicant petitions under 37 C.F.R. 1.97(d) for the consideration of this IDS. Under 37 CFR 1.17(i) a check in the amount of \$180.00 is enclosed. Counsel certifies that, upon information and belief, each item of information listed herein was either (i) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the IDS; or (ii) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

2. In accordance with 37 C.F.R. 1.98, this IDS includes a list (e.g., form PTO/SB/08) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document listed is attached, except as explained below.

(check boxes A, B and/or C and fill in blanks, if appropriate.)

- ☐ A. Pursuant to the Notice issued by the United States Patent and Trademark Office dated July 11, 2003 waiving the requirements of 37 C.F.R. § 1.98(a)(2)(i), a copy/copies of the United States Patent on PTO/SB08 is/are not being submitted.
- ☐ B. Document(s) \_\_\_\_\_ is (are) deemed substantially cumulative to document(s) \_\_\_\_\_, and, in accordance with 1.98(c), only a copy of each of the latter documents is enclosed.
- ☐ C. Certain documents were previously cited by or submitted to the Office in the following prior applications, which are relied upon under 35 U.S.C. 120:

[SERIAL NO. & FILING DATE].

Applicant identifies these documents by attaching hereto copies of the forms PTO-892, PTO-1449 and/or PTO/SB/08 from the files of the prior application(s) or a fresh PTO/SB/08 listing these documents, and request that they be considered and made of record in accordance with 1.98(d). Per 37 CFR 1.98(d), copies of these documents need not be filed in this application.

☐ 3. Cite Nos. \_\_\_\_\_ are not in the English language. In accordance with 1.98(c), Applicant states:

- ☐ An English translation of each document (or of the pertinent portions thereof), or a copy of each corresponding English-language patent or application, or English-language abstract (or claim) is enclosed.
- ☐ The requirement for a concise explanation of the relevance of any foreign language document is satisfied by the attached search report; citation of the documents cited in the search report shall not be construed as an admission that they are or are considered to be, material to patentability of the subject matter claimed herein (See MPEP §609).
- ☐ A concise explanation of the relevance of document(s) \_\_\_\_\_ is set forth as follows: [Insert concise explanation of relevance]
- ☐ A concise explanation of the relevance of document(s) \_\_\_\_\_ can be found on page(s) \_\_\_\_\_ of the specification.
- ☐ A concise explanation of document(s) \_\_\_\_\_ can be found on the attached sheet.

☐ 4. No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 in the preamble to the final rules; 1135 OG 13 at 20).

☒ 5. Other information being provided for the examiner's consideration follows:

An International Search Report, dated April 13, 2004, which issued during the prosecution of International Application No. PCT/JP03/16496 which corresponds to the present application, is enclosed.

6. In accordance with 37 C.F.R. 1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless other-wise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

JC09 Rec'd PCT/PTO 21 JUN 2009

**CROSS REFERENCE UNDER 37 C.F.R. (1.78 TO RELATED APPLICATIONS**

Pursuant to 37 C.F.R. ( 1.78, Applicant notes that the above-identified patent application may be related to the following U.S. Patent Applications:

(1) U.S. Patent Application Serial No \_\_\_\_\_, filed \_\_\_\_\_.

Early and favorable consideration is earnestly solicited.

Respectfully submitted,

*Sandra Lee (Reg. No. 51,932) for*

Adda C. Gogoris

Registration No. 29,714

Attorney for Applicant(s)

DARBY & DARBY P.C.  
P.O. Box 5257  
New York, N.Y. 10150-5257  
(212) 527-7700

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PTO/SB/08a/b (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>			<b>Complete if Known</b>		
			Application Number	Not Yet Assigned	
			Filing Date	Concurrently Herewith	
			First Named Inventor	Kunihiro Ohta	
			Art Unit	N/A	
			Examiner Name	Not Yet Assigned	
Sheet	1	of	2	Attorney Docket Number	04393/0203024-USO

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>	
	CA	Nickoloff, J.A., "Transcription Enhances Intra chromosomal Homologous Recombination in Mammalian Cells", Mol. Cell. Biol., (1992), Vol. 12, No. 12, pages 5311-5318, full text.		
	CB	Buerstedde, J. and Takeda, S., "Increased Ratio of Targeted to Random Integration after Transfection of Chicken B. Cell Lines", Cell., (1991), Vol. 67, No. 1, pages 179-188, full text.		
	CC	Chen, J., et al., "Mutations of the intronic IgH enhancer and its flanking sequences differentially affect accessibility of the JH locus", EMBO. J., (1993), Vol. 12, No. 12, pages 4635 to 4645, full text.		
	CD	Forrester, W.C., et al., "Dependence of Enhancer-Mediated Transcription of Immunoglobulin $\mu$ Gene on Nuclear Matrix Attachment Regions", Science, (1994), Vol. 265, pages 1221-1225, full text.		
	CE	Bachl, J. and Wabl, M., "Enhancers of hypermutation", Immunogenetics, (1996), Vol. 45, No. 1, pages 59-64, full text.		
	CF	Betz, A.G. et al., "Element Regulating Somatic Hypermutation of an Immunoglobulin $\kappa$ Gene: Critical Role for the Intron Enhancer/Matrix Attachment Region", Cell, (1994), Vol. 77, No. 2, pages 239-248, full text.		
	CG	Bachl, J. and Wabl, M., "An Immunoglobulin mutator targets G-C base pairs", Proc. Natl. Acad. Sci. USA, (1996), Vol. 93, pages 851-855, full text.		
	CH	Lahti, J.M., "Use of Gene Knockouts in Cultured Cells to Study Apoptosis", Methods, (1999), Vol. 17, No. 4, pages 305-312, full text.		
	CI	Siebos, R. and Taylor, J.A., "A Novel Host Cell Reactivation Assay to Assess Homologous recombination Capacity in Human Cancer Cell Lines", Biochemical and Biophysical Research Communications, (2001), Vol. 281, No. 1, pages 212-219, full text.		
	CJ	Arakawa, H., et al., "Requirement of the Activation-Induced Deaminase (AID) gene for Immunoglobulin Gene Conversion", Science, (2002), Vol. 295, pages 1301-1306, full text.		
Examiner Signature				Date Considered

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Approved for use through 07/31/2006. OMB 0651-0031

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				Application Number	Not Yet Assigned
				Filing Date	Concurrently Herewith
				First Named Inventor	Kunihiro Ohta
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	2	of	2	Attorney Docket Number	04393/0203024-US0

	CK	Phi-Van, L. and Stratling, W.H., "Dissection of the Ability of the Chicken Lysozyme Gene 5' Matrix Attachment Region To Stimulate Transgene Expression and to Dampen Position Effects", <i>Biochemistry</i> (1996), Vol. 35, No. 33, pages 10735-10742.	
	CL	Bulfone-Paus, S., et al., "The Chicken Immunoglobulin $\lambda$ light chain gene is transcriptionally controlled by a modularly organized enhancer and an octamer-dependent silencer", <i>Nucleic Acids Research</i> , (1995), Vol. 23, No. 11, pages 1997-2005.	
	CM	Lauster, R., "Promoter, enhancer and silencer elements regulate rearrangement of an immunoglobulin transgene", <i>The EMBO Journal</i> , (1993), Vol. 12, No. 12, pages 4615-4623.	
	CN	Israel, D. and Kaufman, R., "Highly inducible expression from vectors containing multiple GRE's in CHO cells overexpressing the glucocorticoid receptor" <i>Nucleic Acids Research</i> (1989), Vol. 17, No. 12, pages 4589-4604.	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
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